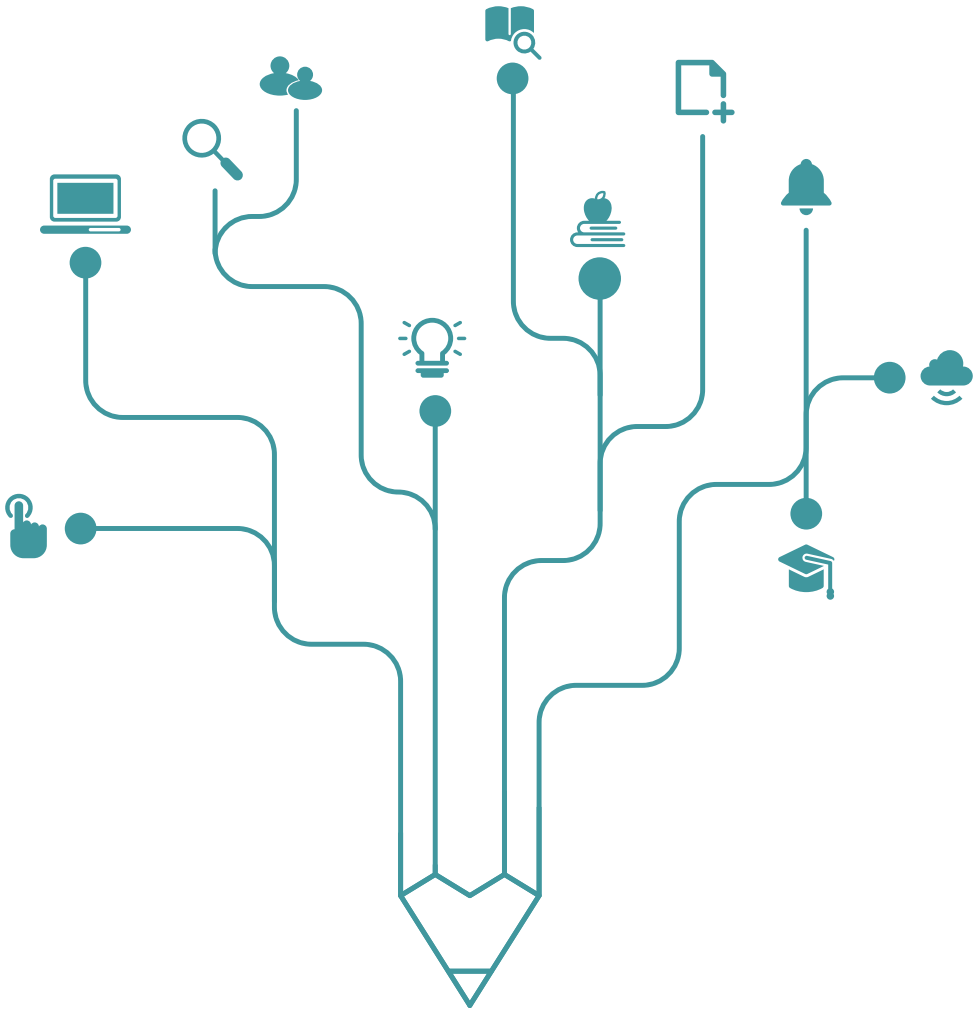
KDIS Working Paper 20-19

# Regulatory Reform for Fostering an Innovation Ecosystem

*Sooyoung Oh (KDI School of Public Policy and Management)*
*Changyong Choi (KDI School of Public Policy and Management)*
*Ju-Ho Lee (KDI School of Public Policy and Management)*



KDI SCHOOL
KDI School of Public Policy and Management

# Regulatory Reform for Fostering an Innovation Ecosystem[1]

Sooyoung Oh, KDI School of Public Policy and Management, 263 Namsejong-ro, Sejong-si, 30149, Republic of Korea. Email: osy@kdis.ac.kr
Changyong Choi, KDI School of Public Policy and Management, 263 Namsejong-ro, Sejong-si, 30149, Republic of Korea. Email: cychoi@kdischool.ac.kr
Ju-Ho Lee, KDI School of Public Policy and Management, 263 Namsejong-ro, Sejong-si, 30149, Republic of Korea. Email: jhl@kdischool.ac.kr

[1] We are grateful to the KDI School of Public Policy and Management for providing financial support.

**Abstract**

Although South Korea has taken various measures related to regulatory reform over the past decades, it has not made significant progress in transforming its regulatory framework. There are still a large number of regulations that are outdated and exist only in South Korea compared to other developed countries. This working paper reviews key measures made in recent years and clarifies critical steps that the country must take to make a successful transition. We first examine the direction of regulatory reform corresponding to the Fourth Industrial Revolution and how developed countries are rapidly moving to conceive the optimal regulatory design to promote innovation. Then, we highlight the major efforts South Korea has made in recent years to initiate regulatory reform and the fundamental challenges that remain. Lastly, we dive deep into regulatory reform for health care innovation, particularly as the government pledges to build a world-class bio-health industry over the next decade. We also approach regulatory reform from a public perspective, discussing how to encourage civic participation through open-minded communication and information-sharing with the public. As the South Korean society lacks trust towards new technologies and data usage, it is crucial to establish credibility of emerging industries as well as a balanced understanding of the potential benefits, ironing out conflicting views between stakeholders.

## Chapter 1: Global shift towards adaptive co-regulation in the post-pandemic era

Rapid advances in technology are disrupting and reshaping every industry and society in the era of the Fourth Industrial Revolution. Emerging technologies such as Artificial Intelligence, robotics, and the Internet of Things are driving the creation of new products, business models, platforms and solutions, from manufacturing and logistics to precision medicine, autonomous cars and virtual assistants. Also, the traditional notions of money and ownership, as well as labour and productivity have been radically redefined with the birth of cryptocurrencies, sharing platforms, automation and the gig economy. Economies can no longer rely on past methods of production, value creation and productivity as emerging technologies will serve as key drivers of economic growth and social development for generations to come in the "new normal" era of hyper-digitalization prompted by the novel coronavirus outbreak in 2020.

New technologies tend to develop faster than the regulations or social structures governing them, while carrying high levels of risk. Outdated regulations fail to support, and can even stifle, innovative research, products and the birth of new industries. Also, the unpredictable nature of the market as well as the valley of death present uncertainty for developers and businesses which is made all the greater by the absence of clear guidelines from authorities. Furthermore, unprecedented complexities arise from the impact of novel technologies on society and individuals, such as the automation of jobs, breach of personal information and privacy; as well as ethical questions that arise from developments in life science like gene-editing and the issue of liability in road accidents caused by self-driving vehicles.

In light of these new challenges, a 2018 KDI study edited by Lee and Choi (Lee, J. & Choi C., 2018) identified the need for a systematic reform on how to regulate technology that breaks the boundaries of traditional technologies and the rules that govern them. First, we proposed ways for regulators to employ flexible approaches that encourage innovative activities, maximising the benefits while minimising negative externalities. Second, we prescribed a "regulatory innovation ecosystem" where all stakeholders of society would shoulder the burden of risk and uncertainty as well as ethical challenges surrounding emerging technologies.

### 1. Fast tracking innovation: paving the way with innovative regulations

In our 2018 study, we proposed three different mechanisms governments could employ to make their regulations flexible and adaptive.

First is the introduction of a "negative system" based on 'permissionless' innovation. In South Korea, most statutes in a "positive" regulatory system are based on the precautionary principle, that lists what the law permits. As all activities without permission are banned, the regulatory

environment is predisposed to being inflexible and preventive of new technologies, and also creates significant blind spots. The positive system is a supplier-oriented regulatory system, which is easy to manage and has a clear standard of punishment, but can lead to a significant increase in regulatory compliance costs for new business models and new markets where uncertainties exist. Therefore, adopting a looser and wide-ranging negative regulation system would allow greater flexibility in legislation, through a comprehensive definition of key terms and concepts, flexible classification, performance-based regulations, and the delegation of statutory powers to subordinate authorities.

Another approach is adopting a regulatory sandbox to enable maximum flexibility in testing new technologies and accelerate the process of commercialization. The regulation sandbox was first introduced in the UK to foster its fintech industry. It lays the legal groundwork for pilot projects where new technologies and business platforms can be tested freely and to their full capacity as all existing regulations can be ignored; or partially or temporarily waived within the boundaries of the sandbox. Many countries, including South Korea, Japan, China, and the United States, have also introduced regulatory sandboxes, with complimentary measures such as preliminary approval and post-regulation to emerging industries.

Third, we suggest a risk-based approach could be employed, following early impact and risk assessment. Regulators could respond and adapt to emerging technologies, introducing regulations only where needed, depending on the level of risk. Taking a case-by-case approach is advisable as a negative regulation system, for instance, doesn't suit all industries or legislative contexts and adopting a universal policy approach would not provide the flexibility needed to support and regulate new forms of businesses. Thus, measures such as pre-regulation, ex-post regulation, interim regulation, administrative guidance, and non-regulation can be applied appropriately, following the assessment of the size and probability of risk for the technology in question. For technologies that fall into the "high risk" category, strict pre-regulation should be placed prior to commercialization, whereas the principle of free entry should apply for technologies that are considered to pose a lower level of risk. In the "low risk" scenario, self-regulation can be implemented while traditional regulators can strengthen oversight, re-evaluation of risks, and apply ex-post regulation where needed.

## 2. Innovation Ecosystems as a Regulatory Framework

Innovation is no longer confined to the laboratories of corporate giants or government institutions, nor is it commissioned under controlled environments and top-down initiatives. The world has been experiencing a democratisation of innovation and technology, through lower costs of technological tools, greater access to information, ideas and networking as well as crowdfunding (Cohen B. and Munoz P. 2016). 3D printing, for instance, allows anything to be printed and

distributed from thousands of miles away, from auto parts to drugs and, potentially, human organs for transplantation which are now undergoing clinical trials. Now, countries that are leading the development of emerging technologies have a healthy landscape of innovation ecosystems which bank on the close proximity and availability of strong university research, entrepreneurial landscape and a quality talent pool, which are interlinked in a continuous virtuous cycle. The most prominent examples of this bottom-up innovation can be found in Silicon Valley in the U.S. and Tel Aviv in Israel which produce some of the world's most cutting-edge technologies and largest IT companies in the world.

While the innovation ecosystem is not a new phenomenon, our study in 2018 broadened the definition to include 'inclusive regulatory innovation," meaning that collaboration between industry, researchers, business actors and civil society is not limited to creating business models, platforms, products, and industries. Stakeholders of the ecosystem should also come together to design optimal regulations to encourage innovative research and development while addressing societal, environmental and ethical concerns. This requires discourse and cooperation from all sectors and a society-wide shift to a "regulatory culture" (Lee J. and Choi C. 2018).

The case for shared regulation between government, businesses, and civil society has been growing strongly in recent years, as digital technologies and services blend the public and private spheres. Governments are being called upon to provide more efficient public services and show greater transparency through digital communication and online government systems. Businesses have become co-facilitators of public governance, developing and leveraging their technologies to accomplish public goals (OECD 2011). Meanwhile, the role of citizens has evolved from simply consuming mass manufactured goods and services to becoming part of the value creation process in the connected, digital economy. As "prosumers" of on-demand, personalized services, sharing platforms and data-driven services, members of the public are shaping and driving industries with the consumption and lifestyle choices they make. Therefore, their greater civic commitment and participation can better inform and shape regulatory design, and help reduce uncertainties for innovators while also consolidating consensus on new social challenges. In 2018, the UK's Digital Charter brought together the government, the tech sector, and businesses and civil society to jointly address the challenges of digitalisation and find relevant solutions.

While the above suggestions were made in the context of South Korea's regulatory environment, they have remained strongly relevant as guidelines for any government to build the optimal regulatory framework to respond to emerging technologies.

The World Economic Forum in 2018 described this as a form of "agile governance" in the Fourth Industrial Revolution Era, highlighting the importance of collaboration between policymakers, industry and citizens in jointly designing regulations that are adaptive, inclusive and sustainable. The United

Kingdom in 2019 laid out a similar regulatory framework to support its Industrial Strategy (2017) which commits to hefty investment in life sciences, AI, robots, technical institutes and to boosting earning power. UK aims to: adopt agile and outcome-based regulatory measures such as the use of voluntary standards, innovation testbeds; stronger public engagement; streamlining regulatory bodies by establishing a new council to oversee regulations and institutions; supporting innovation ecosystems by enhancing research and development (R&D) and nurturing a talent pool through more adaptive education. The European Union and Japan's Society 5.0 and New Economic Policy Package (2018) have also identified the need for flexible, adaptive regulations to harness the core future technologies.

This paper aims to review how far South Korea has progressed in terms of reforming its regulations to accommodate key areas of innovation, based on the recommendations we made in 2018. In the next two chapters, we examine the regulatory changes that have taken place in the South Korean context since 2018, based on recent data and publications along with interviews we conducted with industry experts, developers and innovative businesses directly involved in regulatory changes. Chapter Two will review efforts to promote the development of major emerging technologies and the utilization of data which is considered the lifeblood of the Fourth Industrial Revolution. In Chapter Three, we will focus on the bio-health sector, as a key sector in most pressing need of reform, especially as it is crucially needed to overcome the burgeoning challenges to public health and it was, this year, designated as a pivotal growth engine under the government's economic strategy. The final chapter will set out basic guidelines on laying the groundwork for a bottom-up innovation ecosystem, based on our previous recommendations, and taking into consideration the recent regulatory developments and challenges.

## Chapter 2: Can South Korea break out of the box?

At the turn of a new decade, South Korea has drawn up a brand "New Deal" to revitalize its economy and renew its technological prowess as a leading global innovator. With over $130 billion earmarked for the initiative, much of the deal will focus on building new engines of economic growth through innovation in the digital and green sectors, mostly in the form of contactless, data-driven services. Over the past five decades, the country has made an astronomical leap from a post-war economy producing textiles and plywood to manufacturing cutting-edge digital devices and semiconductors, and biosimilars. Its accomplishments have received much accolade from the global community, with Nature Index 2020 even dedicating a special edition that highlighted the country's top-down innovation that produced the likes of Samsung, LG Electronics and SK Hynix.

However, amid the Fourth Industrial Era, South Korea's traditional cash cow industries such as semiconductors, automobiles and shipbuilding are waning in value and competitive advantage, as global competitors are rapidly catching up and new value chains are being created. As new, game-changing technologies emerge, and become broadly established and adopted across the world, it has become crucial to become a first mover in order to become the industry standard-bearer and leverage the network effect, given the winner-takes-all nature of the global tech market. Governments everywhere are rising to the challenge, having set out their respective industrial strategies for emerging technologies, and most crucially, new regulatory frameworks that are agile, flexible, and responsive which promote competition and innovation.

South Korea has not been able to respond rapidly to the changing global dynamics. Despite the explosive nationwide hype over Artificial Intelligence triggered by the historic showdown of Go player Lee Se-dol and Deep Mind's AlphaGo in 2016, there has been no concrete national strategy for AI until December last year, far behind countries like the United Kingdom and Japan. There have also been no South Korean killer apps or platforms taking over the global market like Netflix and TikTok, nor has the country yet to boast of future cars like Tesla or Nikolo. In medicine, South Korea excels in producing biosimilars, with production capacity second in the world after the U.S. and the country received global attention in 2020 for its rapid development of COVID-19 test kits after the first local infection case was reported. However, no blockbuster drug, or ground-breaking health care device has emerged from the country and, as lamented every year, South Korea has yet to see a Nobel Prize-winning scientist.

The lack of progress is disappointing, considering the country's highly-educated workforce, large number of patent filings and sizeable investment in research and development (R&D) the scale of which is second after Israel in scale relative to gross domestic product (GDP), and a series of attempts by one administration after another to grow a vibrant landscape of start-ups. Compared to Israel's Tel Aviv, which is considered the world's sixth major start-up ecosystem after the iconic Silicon Valley, Seoul only made the Top 30 this year (no. 20), primarily for its strength in R&D.

For years, experts have pointed to regulatory barriers, a lack of ecosystem coordination, based on a "positive regulatory system" as key factors that have stifled creative research and the development of novel technologies and solutions. This has subsequently compromised the country's global competitiveness in emerging industries (Lee J. and Choi C. 2018), causing the country to fall further behind in the race to develop Fourth Industrial Revolution technologies. The World Competitiveness Ranking scored South Korea at 28th place in 2019, with government efficiency falling by two places from 29th to 31st.

In order to overcome this critical government failure, we believe a regulatory ecosystem must be established, in line with our recommendations made in 2018. We propose a systematic overhaul of the current regulatory system that inhibits competition and innovation, an independent control tower to spearhead regulatory innovation, along with improved support for start-ups, and a platform for social deliberation and consensus.

CURRENT GOVERNMENT INITIATIVES

Over the past 4 years, both industry and academia have called for the government to ease its outdated regulatory regime characterized by "positive regulations" and an overbearing bureaucracy, which, together, have imposed a culture of risk aversion, rather than promote and reward innovation.

Centered on the ''precautionary principle,' positive regulations only allow listed or stated activities in developing new technologies, thereby outlawing any activity that has not been permitted by law. This white-list approach makes it infeasible for innovative activities to take place, from the stages of research to commercialization, as they do not fit into the realm of existing regulations. For instance, South Korea's laws on road safety and the environment, for instance, currently do not recognize robots as a vehicle, thus effectively bans them from being tested or used on public roads as delivery devices. Privacy regulations also limit the development of self-driving technology. Camera footage is crucial to helping unmanned mobility devices detect, identify and remember the environment around them. However, under current regulations, video cameras cannot record people's faces or any attributes that could identify an individual. Other key areas of emerging technologies are similarly hindered by such outdated regulations, not only in the stages of development, but also commercialization that could grow whole new industries. For instance, restrictions on using Direct-to-Customer (DTC) genetics test kits have hindered local companies from developing products like '23 and Me' which could benefit personal, preventative health care and even grow an entire gene-based industry around it, from DNA-based meal services and cosmetic products.

The government has implemented several measures we recommended (Lee J. and Choi 2018), such as adopting a regulatory sandbox and introducing legislative revisions to fast-track reviews on new medical technologies. It has also implemented the revised 'three data laws' in August 2020, after years of parliamentary gridlock.

**Key changes in '3 Data Laws'**

**Personal Information Protection Act** (PIPA)

Clarified concept of 'personal data,' and 'pseudonymized data' and removed anonymized data from the scope of personal data).

Clarified the scope of permitted processing of pseudonymized information:

1. Allowing use of pseudonymized data for statistical, scientific research, or public interest record-keeping purposes
2. Allowing pseudonymized data to be combined through specialized agencies.

- Imposed new restrictions upon pseudonymized data processing.
- Allowing use and transfer/release of personal data without obtaining consent, if the purpose is related to the original purpose of data collection.

- Enhanced the Personal Data Protection Commission (PDPC)'s authority and powers.

**Network Act**

- Removed provisions related to the protection of personal data to prevent overlap with PIPA.
- Provided a legal basis for delegating partial authority to the South Korean Communications Office from the South Korean Communications Commission (KCC)

**Credit Information Act**

- Clarified the legal basis for analysing and using big data in the finance sector.
- Streamlined legal framework to minimize overlaps with provisions under PIPA.
- Introduced MyData platform (providing consolidated-basis personal information verification and credit information and/or asset management)
- Strengthened the protection of personal data in the finance sector.

**Regulatory Sandbox**

South Korea's regulatory sandbox took effect in January 2019, as a two-year mechanism for exempting or suspending regulations on new technologies to develop goods and services that were previously unavailable due to such rules. The aim is for businesses test and optimize their technologies and services in a controlled environment, or a limited market, while the government can swiftly improve related regulations based on real-life data. The sandbox period can be extended once.

However, without fully embracing a regulatory framework that is conducive to innovation, the changes have largely remained cosmetic. Firms within the sandbox are still required to go through lengthy legal reviews to check for regulatory barriers. Upon discovering legal ambiguities, they must apply for a temporary waiver or special exemption for demonstration. As the long and complex approval procedures hinder business for participating firms, they are grappling with lost time and growing maintenance costs, making it uncertain whether they will be able to take their products to market by the time their sandbox period expires, or whether they can keep afloat as a business. There is also growing concern and doubt on

whether authorities are willing to change regulations given the blame avoidance culture (Seoul Economic Daily 2020).

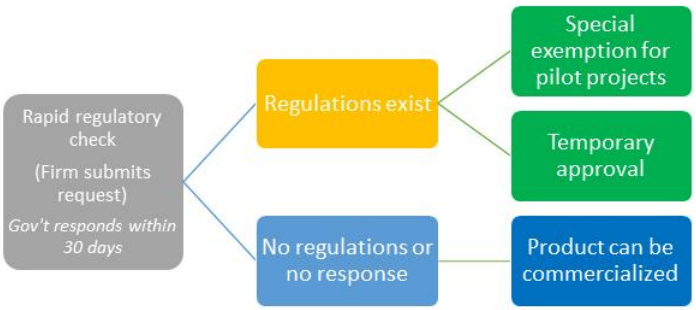
Meanwhile, the country's revised data laws have also generated scepticism over whether it can create a multibillion dollar 'data dam' that will fuel innovative products and services. The majority of firms remain cautious about processing and utilizing data, as the recent revisions have not provided sufficient clarity on major sticking points, such as the additional usage of data and the acceptable standards of pseudonymization particularly in key technologies like video processing for self-driving cars. Also, stringent terms on punishing violation cases add to their nervousness around using data (Kim 2020).

In 2019, a survey of 500 companies found 30.6 percent were pessimistic about the impact of the administration's recent regulatory reforms, which double the proportion of optimists (15.6 percent). The responses were the opposite of the 2018 survey results where 32 percent were optimistic while 10.6 percent were pessimistic (KERI 2019). More than a third of the firms that were dissatisfied with regulatory reform cited "insufficiency in resolving invisible barriers and blind spots," "lack of regulatory improvement," unwilling attitude among public servants" and the "creation and strengthening of regulations."

In the academic realm, the government holds excessive control over research and development, discouraging autonomy and creativity of the scientific community. By interloping in the innovation process, from deciding which technologies, products, or researchers to support, it is difficult to see the kind of bottom-up innovation that takes place in Israel where the country's Chief Scientist formulates the framework of scientific and industrial R&D. According to a survey of 75 members of Korean Academy of Science and Technology, only 22.6 percent of all respondents were satisfied with how the government selects and evaluates R&D projects. More than half the respondents believed bureaucrats showed 'bias in project planning,' 'unclear standards of evaluation,' and ungrounded 'restrictions on participation'. As civil servants themselves are evaluated according to the quantity of their achievements, they tend to select short-term projects that would deliver maximum performance (Song 2020).

**Case: Regulatory Sandbox**

The regulatory sandbox was adopted in January 2019, to allow new products and services to be tested and developed under a controlled environment, until regulatory adjustments are made if the technology is deemed appropriate for use. Firms can extend their 2-year period once, allowing them a total of four years inside the sandbox.




Source: Ministry of Trade, Industry and Energy (2019)

Upon the one-year mark of introducing the sandbox, the government had approved 239 new products and services to be tested within the system including 47 cases in ICT, 52 cases in convergence industries, and 102 cases in the financial sector. However, even with the regulatory sandbox in effect, strong uncertainty remains for developers (Jung 2020). Firms are complaining there are just as many barriers within the sandbox, as they need to acquire additional approval to test technologies that breach or contradict existing laws. This means developers must still devote a large amount of time reviewing regulations to determine whether they are breaking any laws, and whether they need to apply for a special permit to test their products (Moon 2020). For instance, self-driving robots need to acquire special permits from the transport ministry to drive their devices across parks and green spaces, as mobility equipment over 9 kilograms is banned from entering green spaces.

Also, developers face growing costs and uncertainty as they wait for approval to test or roll out their products. DTC genetic testing firms, for example, must gain the Institutional Review Board's approval for each and every type of health indicator their test kits can offer consumers, such as the level of Vitamin D in their system or the level of genetic disposition to contracting certain diseases. While these services require no such approval in countries like Belgium, Canada and the UK, the firms inside South Korea's sandbox must go through multiple review procedures, to obtain all the permission and clearance they need to test their technologies. One of the biggest firms inside the sandbox, Macrogen, has gone through five review procedures yet only received permission to test 6 out of the 24 indicators it sought approval for more than a year, as more and more regulatory issues kept surfacing (Lee 2020).

The focus should not be about the number of firms entering the sandbox but what comes out of it. Start-ups are uncertain whether they will be able to sustain themselves financially until they receive clearance for the technologies they need to test. Another major point of concern is whether the

government would revise regulations accordingly, and in a timely manner, by the time the sandbox period expires.

## POLICY RECOMMENDATIONS

In order to shift from a "fast follower" to "first mover," an ecosystem approach to be at the heart of South Korea's regulatory design (Lee J. and Choi C. 2018). We maintain our 2018 recommendations on building a pro-competition and pro-innovation regime, with the government transforming its role from a controller to enabler of innovation.

First, there needs to be an effective decentralization of regulatory powers, bestowing more autonomy and authority to industry experts and research intermediaries when it comes to .designating Starting with R&D, the government should step back from its excessive involvement in every stage of the innovation process, from designating research priorities to selecting projects and participating firms. Instead, we suggest regulators enhance autonomy of intermediaries that will facilitate "high-risk/high-payoff" projects, based on a competitive selection process of R&D areas and research partners. Delegating highly qualified field specialists and industry experts would allow for more informed and efficient measures to support the growth of new technologies and industries, which are rapidly evolving and changing according to market demand. As seen in the United States' Defence Advanced Research Projects Agency (DARPA), hiring technically-accomplished experts as program managers who have the authority and responsibility to propose and implement R&D programs has been the backbone of the country's world-class innovations (Bonvillian et al. 2019). The managers determine the scope, rationale and technologies as well as the metrics of measuring progress and budget for each project, which is facilitated by outside labs, experts and firms. Breakthrough technologies discovered in the process such as robotic arms to handle explosive content have led to the most widely used commercial technologies today including the Global Position System (GPS) and Apple's voice assistant Siri.

Also, in terms of both R&D and commercial practices, the government should accept industry standards and enable self-regulation, especially in data usage. As mentioned in the previous chapter, most scientific communities have established their own standards and principles which outpace government-drafted regulations as they adapt faster to changes in technology, market and industry. Therefore, it is more efficient to entrust expert communities with establishing the rules, which would not only save bureaucratic time and resources but also develop trust between industry and government and increase likelihood of compliance.

Furthermore, as businesses tend to respond more rapidly and sensitively to market demand, it is in their interest to develop products and practice standards that benefit consumers and are socially responsible. Thus, rather than trying to set the rules, the government should rather focus on reviewing and overseeing compliance to ensure societal interests are met, and supporting consumer and citizens' rights.

Second, a permanent control tower is needed as a hub and constant driver of regulatory innovation (Lee J. and Choi C. 2018), conducting oversight and coordination over decentralized regulatory forces as mentioned above. While there are currently several executive committees and government bodies dedicated

to regulatory reform their roles and powers have been sensitive to political changes, limiting their scope and capacity to pursue long-term strategies for innovation. The Regulatory Reform Committee, for instance, has been subject to downsizing and expansion, depending on the administration. In 2005, it made 367 cases of recommendations but only 40 cases in 2016. In 2000, 94 withdrawal recommendations were only 4 in 2015 and 2016. Also, its membership is mostly limited to government ministers, and a panel of experts from economic or legal backgrounds, who only convene when an agenda is raised. The Prime Minister's office has its own Regulatory Reform Office, which plays a key role in reviewing thousands of proposals received from central government bodies. However, it has been understaffed for years, and is also subject to political changes. Thus, it has been systematically difficult to promote long-term regulatory reform tasks, let alone accumulate sufficient know-how necessary for regulatory reform within the given term. While the Fourth Industrial Revolution Committee, which was established in 2017 with the purpose of shaping and leading the advancement of emerging technologies, it has been criticized for its failure to coordinate innovation policies across government ministries, as well as its lack of initiative on regulatory reform in key areas such as mobility platforms and artificial intelligence. The committee was also blasted for the frequent absence of ministers at committee meetings, marking only a 25 percent attendance rate (Choi I. 2020).

Given these constraints to the consistency of reform, we propose establishing a permanent and independent reform committee within the government to coordinate and drive regulatory changes, irrespective of the political environment. The organization should oversee the review of pertinent regulations, consult government bodies, and, most crucially, plan and initiate priorities and long-term strategies for regulatory reform. To ensure its neutrality and accountability, an organization should be able to allocate its own budget to effectively and appoint personnel independently and competitively. A number of advanced economies have already set out to establish such an institution for regulatory reform. Germany's Nationaler Normenkontrollrat was established in 2006, while the UK set up its own Regulatory Policy Committee in 2009. The U.S. also installed the Office of Information and Regulatory Affairs (ORIA) for more stable regulatory management, within the Office of Management and Budget (OMB). In 2015, the European Union also conducted a Regulatory Scrutiny Board (RSB) was installed to strengthen the independence and accountability of regulatory reform agencies (Lee M. 2017). These cases demonstrate the necessity of making regulatory reform committees permanent and visibly independent to ensure that there is neither short-term political interference nor any type of bias or favouritism towards or against particular players (Bew P. 2016).

A new regulatory reform committee would also require greater diversity of participants to enable an efficient, democratic regulatory ecosystem. Regulators should actively engage with representatives of industry, experts, and civic groups to include them in process of regulatory reform and encourage positive attitudes towards compliance. In this regard, the body should broaden and strengthen cooperation with

expert groups and research institutions such as Korea Development Institute, where policy professionals are already conducting extensive research on regulatory reform and innovation. The involvement of research institutions could contribute significant value in the regulatory reform process, not only providing high technical support in analysis and design but also serve as neutral actors which is likely to enhance public trust and confidence (OECD 2017).

Third, public deliberation must become a core, established part of regulatory reform, especially in the era of the Fourth Industrial Revolution, where the benefits of technology are expected to trickle down to the individual with increasingly intelligent, connected, and personalized solutions. At the same time, new risks have surfaced in privacy, cybersecurity and jobs, as emerging technologies are largely driven by data consisting of personal information and enable the automation of traditional human jobs. Thus, it is vital to include citizens when addressing fundamental questions such as: whether or to what extent new technologies should be adopted; who would benefit or become disadvantaged as a result, and what ethical concerns would arise from such technologies.

However, in South Korea, civil society has rarely been part of the debate concerning emerging technologies. The most outspoken groups influencing regulatory design have been businesses, labour unions and activist groups who are strongly inclined to resist new technologies and changes in the market.

As the wider population has been grossly unrepresented, regulations have become misaligned with public sentiment and consumer demand leading to both government and market failure. The country has not been short of such examples – the mobility sector being the most notoriously affected. For instance, an overwhelming number of South Koreans chose to use carpool app Tada, which garnered 1.7 million users before parliament passed a bill to outlaw it in March 2020. However, the users' needs for an affordable carpooling service was not taken into consideration and the government heeded the voice of taxi unions before deciding to ban the service from operating. It is the same situation with the question of adopting telemedicine in South Korea. Despite the growing need for affordable and accessible medical care, and the largely positive response from patients who have used telemedicine, the debate is being dominated by doctors' unions who fear technology will dislodge their profit model and introduce new competitors.

Thus, it is crucial to include civil society as part of a regulatory innovation ecosystem. Regulators must commit to public engagement and build it in a way that reaches beyond traditionally interested groups and individual; and seek to connect with people from all walks and backgrounds. In addition to advancing democratic deliberation, the participation of the public could help rationalize and strengthen the case for regulatory changes in sensitive issues, especially in a country like South Korea where issues are heavily politicized or skewed by interest groups. In the UK, innovation-related authorities held over 20 roundtables across the country, involving over 250 organisations to form the government's National Data Strategy in 2019. Through the process, the government engaged with academics, civil society, small and medium-sized

enterprises and public sector organisations. The findings from these roundtables became the basis for the UK's strategy and regulatory design for emerging data-based technologies (Roberts 2019).
Given South Korea's advanced digital infrastructure and high accessibility to social media platforms, there are many ways to inform and encourage citizens to assume their role as a stakeholder in the innovation ecosystem. We believe this should be achieved through public deliberation in the following ways:

First, in order to increase citizen participation in the process of regulatory reform, it is necessary to determine who should decide the contents of regulation and the method of enforcement; the relationship between these actors, and how their interests and conflict structures are organized. Especially with the increasing use of social media and platform-based services, in which consumers are also becoming part of the value creation process, it is difficult to accurately grasp the power relations between corporations and citizens; and determining what should be subject to regulation. Therefore, the agenda should be raised by the citizens themselves, through a bottom-up, deliberative process, as part of regular discussions with industry experts. As a result of these interactions and potential relationships formed in the process, the discussions could generate collective intelligence that not only inform the experts of public opinion but also provide opportunities for mutual learning, understanding and empathy, leading to a higher level of social integration (Lee J. and Choi C. 2018).

Second, the scope of these discussions should be unlimited and distinguished from government-led and expert-oriented discussions -- the bounds of which are constrained to set agendas and formalities. However, as a prerequisite to such citizen discussions, it is necessary to improve public understanding and literacy of regulatory issues, overcoming the asymmetry of information. In order to transparently and accurately convey relevant facts to citizens, it is necessary to clarify specialized terms, concepts and expressions, and provide content and audio-visual materials in various formats, such as storytelling and infographics. In other words, civic and political literacy must be cultivated simultaneously, in order for citizens to holistically examine the interconnectedness of various issues and factors at hand, in the process of developing social issues into a regulatory agenda.

Third, previous studies have shown a perceived opportunity cost of citizen-perceived participation as one of the factors influencing the awareness and evaluation of each citizen participating in the democratic process (McAdam, McCarthy, and Zald 1996). In other words, for citizens to participate in debate and for society to develop rational democracy, it is necessary to establish a system of recognition and evaluation that citizens have less social and economic burden. Therefore, in the institutional system, it is necessary to efficiently manage the cost of public discussion and communication, and to establish an economic process so that this approach can positively affect citizens' participation in discussions and policy deliberation. As such, for the policy process of a more mature civil society, it is necessary to increase the social responsibility of the participants by clarifying the scope and limitations of the confidentiality of the policy information disclosed in the discussion.

Fourth, public forums should be designed to stimulate and leverage interpersonal communication, as a strategic approach. By forming relationships and stirring creativity among participants, the discussions should trigger the individual's intellectual flexibility and enable rational communication between groups, leading them to engage in meaningful dialogue actively and creatively, and generate collective intelligence. This is vital in the context of the South Korean society which remains rigid and conservative towards public debates and open discussions. It may perhaps be necessary to prepare measures to prevent Confucian values and common psychological mechanisms from being ignited and hindering the deliberative process.
As South Korea looks to bolster the development of contactless technologies and services, as a means of recovering from the COVID-19 crisis, building a digital public forum could mark a promising start for greater public dialogue. A new culture of digital discourse could be fostered, helping overcome the traditional social mechanisms such as indirect communication and vertical collectivism.

South Korea can no longer rely on its top-down approach to economic growth, amid constantly changing dynamics of a hyper-digital world and a winner-takes-all market. To move forward and unlock the benefits of the Fourth Industrial Revolution, an ecosystem is needed to propel the country’s status of fast follower to a first mover in the global market. However, without fundamental changes to regulatory framework, South Korea cannot make the transition.

## CHAPTER 3: BUILDING BIO-HEALTH INNOVATION ECOSYSTEM

The novel coronavirus outbreak of 2020 has highlighted the strong capacity and flexibility of South Korea's medical innovation, as local firms quickly developed highly efficient rapid test kits and rolled out high-tech digital solutions to trace and isolate those infected. The international accolade and demand for South Korean bio-health products has given rise to wide anticipation that the country will embark upon a golden age of bio-health, which comprises medicines, medical devices and health management services. The current administration has laid out this aspiration in its 2020 New Deal strategy, and strategies on nurturing ten core industries for future economic growth.

Going forward, South Korea stands at a critical juncture as the world shifts towards 'precision medicine' with the goal of 4Ps: preventive, personalized, predictive and precision medicine. Faced with the mounting costs of accommodating a rapidly ageing population and increasing cases of chronic and mental illnesses, a growing number of countries including the U.S., UK, China, and those in the European Union are focusing on developing key breakthrough technologies to treat severe illness, find cures for rare diseases, and overall, improve public health and well-being. The development and deployment of these medical innovations are expected to proliferate with the infusion of AI, Big Data, connected devices and blockchain technology. The Human Genome Project, for instance, which incurred 2.7 billion dollars and took 13 years to complete. However, genome sequencing cost less than 1,000 dollars in 2017 and took less than 48 hours, (Ministry of Health and Welfare 2019). In this way, advancement in emerging technology is helping make medicine much more precise, accessible and cost-efficient than ever before for overstretched health care systems everywhere. Not only that, but new bio-health technology is highly lucrative, expected to outpace the market growth of traditional industries such as automobiles and shipbuilding (Ministry of Health and Welfare 2019).

Amid competition in a winner-takes-all landscape, regulatory flexibility is needed for innovators to test new ideas, technologies and products that lead the 'biological century' as coined by the World Economic Forum (WEF 2018). Efforts require more than seizing the momentum and the usual combination of investment and support for major industry players. This is especially true for South Korea has shown astonishing adeptness in "fast followership" in developing biologics and medical devices, ranking the world's second and ninth in market share respectively (MDFS 2020). However, the country falls behind in innovation, with the patents and breakthrough findings rarely producing commercial success. Only one out of 150 major global start-ups in bio-health is in South Korea, according to CB Insights. Medical innovation in the country has been limited due to a restrictive regulatory culture, fragmented efforts in R&D and lack of risk funding to enable developers to cross the Valley of Death (KHIDI 2020).

In 2018, Scientific American's Worldview report evaluated 54 nations' competitiveness in the biotech sector, evaluating seven categories: productivity, intellectual property (IP) protection, intensity, enterprise support, education/workforce, foundations, and policy & stability. South Korea ranked 26th, down from 24th in 2016. By category, it ranked first in terms of infrastructure, as in 2016, but scored lower (6.2 out of

10) in Policy and Stability, which measures the competitiveness of government efficiency, regulation, and law. Korea's intellectual property rights protection competitiveness was also relatively low, scoring 5.1 out of 10.

In order to shift gears from fast follower to innovator in breakthrough bio-health technology, regulatory reform is needed. A new regulatory framework must lay the groundwork for steadfast, systematic, and system-wide support from basic research to regenerative medicine.

## 1. GOVERNMENT INITIATIVES

### A. SOUTH KOREA'S NEW DEAL

South Korea Biologics firms in the country, led by Samsung Bioepis and Celltrion, have the capacity to produce around 520,000 liters of drugs per year, coming second to the U.S., and filing the third highest number of patents related to biopharmaceuticals (MDFS 2020). As of June 2020, 29 new drugs have been developed in South Korea with an average of two to three new drugs hitting the market every year. The country is also an active exporter of medical devices, ranking 9th in the world as of 2018, mostly for its ultrasound imaging systems, dental implants, and soft contact lenses. Exports grew 14.1 percent on-year, hitting US$3.6 billion (KHISDI 2020).

The government in 2019 revealed a ten-year plan for 2030, by which they aim to triple the country's share of new medicine and health devices in the world market to 6 percent from the current 1.8 percent. Under the plan, South Korea will aim to hit 50 billion dollars in bio-health exports and create over one million jobs in the process.
The specific goals include:

- Building five major Big Data platforms to spur advancement in the bio-health industry, based on the data of 1 million people by 2029
- Creating new drugs and medical devices by expanding government spending in R&D to $3.3 billion by 2025
- Injecting more than $1.6 billion into establishing an ecosystem and funding for firms in form of financial subsidies and tax benefits

The current administration reaffirmed the administration's commitment to this plan in 2020, highlighting bio-health, future cars and system semiconductors as three core engines of future growth for the South Korean economy. Particularly with the rapid digitalization of core services, South Korea's 'New Deal' also

commits to the use of data and AI in core industries including bio-health as well contactless services, alluding to telemedicine which is currently banned in the country.

Furthermore, the trade, health, science, and drug safety ministries in May announced they would begin a joint medical device R&D project worth 980 million dollars over the next five years. The pan-government effort would aim to develop core components and foundational technologies to create ground-breaking innovations, and roll out regulatory support to spur such developments.

### B. REGULATORY REFORMS ENACTED BY LAW

After years of heated parliamentary debate, key regulatory reforms were made last year with legislation passed to promote the growth of bio-health industries. We first proposed and laid out the blueprint for these acts in 2017 (Lee J. and Choi C. 2018), as crucial instruments in paving the way for key medical technologies and discoveries to be made in the country.

### 1) Regenerative Medicine Act

First proposed in Dec. 2015, the Regenerative Medicine Act was finally enacted in 2019 and goes into effect from August 2020. By streamlining overlapping regulations related to biopharmaceuticals which were scattered across the Pharmacy (or Pharmaceutical Affairs Act) law and Bioethics and Safety Act, the act paves the way for conducting clinical research on advanced regenerative medicine (cell therapy, gene therapy, tissue engineering therapy, and etc.), which faced long and grueling approval procedures in the past. First, the act defines the categories of regenerative biomedicine as cell therapies, gene therapies, tissue engineering systems, and combination products. In particular, when certain requirements are met during clinical research on regenerative medicine, the act introduces a rapid approval and delivery system such as customized review, accelerated approval, and conditional approval; and establishes a safety management system. These fast-track would enable a speedier review process for regenerative medicine, prioritizing them above other drugs, and in case of severe illnesses like cancer or rare diseases, the product could be delivered to the patient based on phase 2 clinical data -- before the efficacy is confirmed by the phase 3 clinical trial. The law introduces a comprehensive safety management system for the development of advanced biopharmaceuticals and equipment, from the stages of cell collection to commercialization, as well as enforcing long-term follow-up investigations.
As a result, the process of developing regenerative medicine can be reduced by three to four years.

### 2) Innovative Medical Devices Act

The Innovative Device Act, which went into effect in May 2020, lays out a separate premarket pathway for the research, development and commercialization of novel medical devices and technologies. It introduces a certification system for "innovative medical device companies" which can enjoy greater state support and opportunities to participate in government projects as well as tax incentives. Also, “innovative devices” can undergo a simplified review and approval process which include exemption from certain pre-approval requirements. The act also sets out a separate safety management and support system for such innovative medical ventures, separate from the Medical Devices Act.

### 3) In Vitro Diagnostics (IVD) Act

The IVD Act was enacted in light of views that IVDs should be regulated separately from other medical devices since they are only used for diagnostic purposes and do not come in contact with the human body. The act aims to expedite market authorization and provide greater support for IVDs,

based on a four-level labelling system that weighs the purpose of use, and the potential risk it has on individual and public health.

In addition to these changes in medical regulation, the National Assembly also revised three key data laws in early 2020, with the purpose of allowing 'pseudonymized' information to be collected and transferred to third parties, under the revised Personal Information and Protection Act (PIPA).

**Personal Information Protection Act (PIPA) & Medical Information**

South Korea's law on personal information, considered one of the strictest privacy regulations in the world, previously limited the transfer of personal data for research activities including in the medical sector. Earlier this year, the National Assembly passed an amendment, allowing pseudonymized data sharing with a third party. The amendment goes into effect in August. However, there remains a lack of clarity on how data should be pseudonymized and what conditions should be met to utilize data without seeking consent from the subject. The issue of medical data generates further ambiguity, as patient information, medical records, and such are deemed "sensitive personally identifiable information" which cannot be processed.

Despite these breakthroughs, these laws only set the tone for bio-health innovation. It is essential to scrap the current precautionary system and adopt a negative' risk-based across all stages of development and commercialization.

## 2. POLICY RECOMMENDATIONS

In 2017, we recommended new legislation that regulate innovative medical devices separately by law and introduce fast-track approval systems to enable the rapid advancement of cutting-edge medical technologies and new pharmaceuticals. Since then, the National Assembly has passed legislation in line with our recommendations. However, the laws have been enacted without fully adopting a "negative" regulatory system, which we deemed as the essential force that drives innovation.

Thus we believe, further efforts must be made to scrap ambiguity and risk-averse laws such as those under the Bioethics and Safety Act and the Medical Service Act which hinder advancements in bio-health, particularly in regenerative medicine and data-driven medicine.

## REGENERATIVE MEDICINE

While the recent regulatory changes mentioned above officially categorizes the types of regenerative medicine and reorganize regulatory procedures to enable rapid development for treatment, the laws continue to impose a positive regulatory system when it comes to human embryo production and utilization. Research of embryonic stem cells plays a central role in regenerative medicine and therapeutics, and also spans the disciplines of tissue engineering and developmental cell biology.

Thus, in accordance with our previous recommendations, we propose the adoption of the following measures on human embryo production and utilization.

First, an act on embryo creation (tentative name) should be enacted to allow the creation of human embryonic stem (hES) cells for broader research purposes than advancing fertility, as permitted in the UK. There should be no limit to the research purpose or types of diseases to be studied in stem cell research, including hES cells. However, the law could ensure research is conducted transparently and ethically by clarifying and regulating the terms of registration of the hES, standard procedures, norms for anonymizing data and personal information protection, and etc. The UK allows creation of human embryos for the procurement of hES cells by law. The original HFE (Human Fertilisation and Embryology) Act allowed the creation of embryos in vitro for specific research projects relating to human reproduction and fertility but not for other purposes. However, in 2001 the Act was amended to broaden the research use of in vitro embryos to include increasing knowledge about embryos, serious and congenital diseases. This enabled the HFEA (Human Fertilisation and Embryology Authority) to grant a limited number of laboratories the license to culture hES cells for research, a major move committing to the development of regenerative medicine (Bryant 2006).

Box. 1

The UK's Human Fertilisation and Embryology (HFE) Act, in 1990, established the Human Fertilisation and Embryology Authority (HFEA) and outlined its responsibilities which include the regulation of hES cell experimentation. The original HFE Act allowed

The current law under the HFE Act (amended) allows research using and creating human embryos for research that relate to one or more of the following purposes:

- To promote advances in the treatment of infertility
- To increase knowledge about the causes of congenital diseases
- To increase knowledge about the causes of miscarriage
- To enhance knowledge in the development of more effective contraception
- Detection of genetic or chromosomal abnormalities before implantation

• To increase knowledge about the development of embryos
• To increase knowledge about serious disease
• To enable any such knowledge to be applied in developing treatment for serious disease.

The law also prohibits some key activities:

• The genetic structure of the cell must not be altered while it forms part of an embryo
• Research embryos must be destroyed on or before 14 days of development
• No embryo created or used in research may be implanted in a woman (or any animal)

While the law should not limit the purpose or scope of research, it should explicitly prohibit those that raise health and safety risks and ethical concerns such as cloning humans, altering the genetic structure of the cell while it forms part of an embryo, or implanting embryos used in research in a woman or animal. The United States, for instance, has no federal policy on human embryo research, except prohibiting federal funding for destroying embryos. By delegating the decision to the state, lawmakers can formulate their own policies and strategies based on the general opinion of their constituents. Brazil, China, France, India, and Israel also do not impose statutory research restrictions for human embryo research but follow international consensus guidelines (Baker Institute). In terms o f following international standards on emerging human gene editing tools such as CRISPR-Cas9, the International Summit on Human Genome Editing, under the Innovative Genome Institute, gathers global experts to discuss the scientific, ethical, and governance issues in such technologies.

Second, open innovation should be encouraged and systematized through legislation, legally expanding the scope of actors beyond the few, privileged institutions. Under the Regenerative Medicine Act, only a small number of designated hospitals, or "research-focused" hospitals, can conduct R&D in regenerative medicine. This effectively excludes other clinicians, researchers and firms from the discovery and innovation process. The act should be revised to allow and support all medical actors research, explore and develop regenerative medicine. Based on this new framework, the government should foster measures to or SMEs, receiving access to workspaces, labs and testing equipment as well as financial support to overcome the death valley. In 2012, the UK's Cell and Gene Catapult, composed of hospital and industry experts, academics, researchers and start-ups, formed a cell and gene therapy cluster in Stevenage. Over the years, diverse training opportunities, networking events, and support measures and facilities including large-scale manufacturing systems have helped small innovators conduct research and bring their therapies to market. The ecosystem now hosts 14 companies in the industry, employing more than 350 people and raising over £680 million from commercial investors with the purpose of advancing cell and gene therapy. The cluster has even attracted GlaxoSmithKline, one of the UK's two biggest pharma companies, which has its research headquarters in Stevenage.

Instead of aiming to hedge risks and only allowing large hospitals and institutions to explore the uncharted waters of regenerative medicine, South Korea should also build an ecosystem that actively supports open, and unlimited, innovation. Also, in 2008, we suggested that: in order to facilitate processing and utilizing healthcare data to build big data, proper standards of usage, as well as clear and specific guidance on deidentification (pseudonymization) and reidentification should be set forth by law (Yu 2018). However, the country has been slow to take such measures, and the ambiguity on data usage remains even after revising the three data laws, in 2020 as mentioned in the previous chapter.

**HEALTH AND PATIENT DATA**

In the age of the Fourth Industrial Revolution, Artificial Intelligence (AI) and other emerging technologies are expected to drive new discoveries in medicine and the advancement of medical technology from smart health devices that help predict and prevent diseases to treating severe conditions such as cancer and organ failure. Fueling this medical revolution is data. From patient information and results of clinical trials stored at hospitals to lifelog data collected by wearable devices and smartphone health apps, Clinical researchers, physicians and users themselves can benefit from data gathered through physiological and biochemical sensors which can aid diagnosis, monitor progress, predict and prevent illness or deterioration of health and promptly adjust or update treatments. Digital health solutions are also expected to lower health care costs -- both in terms of public funds and also out-of-pocket spending. The UK has been investing heavily in Artificial Intelligence in the National Healthcare Service (NHS) to "improve outcomes in the NHS and, ultimately, to reduce cost" (Milburn 2020).

In South Korea, there is a great wealth of health data accumulated by the public health insurance system, as well as large general hospitals, with the country's Electronic Medical Records (EMR) adoption rate well over 90 percent (Park 2017). Such data could be utilized to improve predictive and preventive medical care as well as advance research and development of new drugs and medical innovations. There has been a build-up of anticipation on fostering South Korea's digital bio-health industry, especially with the country's information privacy law (PIPA) being amended to allow pseudonymized information to be shared without prior permission. The government has, also, pledged to leverage the country's massive data pool by creating a nationwide health database and encourage data-fuelled innovations to advance the bio-health sector.

However, procuring biospecimens and medical information needed for research has been an almost impossible feat over the years due to regulations under the Bioethics and Safety Act. First, the Act which strictly prohibits the use of such data for both research and commercial purposes, unless the subject of research or donor has given written consent which is subsequently reviewed by the Bioethics Committee. Second, the specific purpose of research must be written in the consent form, thus making it impossible to conduct secondary research beyond the initial purpose in the future. Third, written consent is also required for biological or medical information to be provided to another researcher or data bank, as well as

anonymizing the information. However, it is costly and impractical to track down every donor to get written consent every time the biomaterial or information is used in research. Furthermore, even after the process of seeking written consent for research as well as anonymization of data, the Bioethics Committee wields the power to approve or disapprove the application. Protecting the privacy of patients is essential, of course, however, in the context of the medical industry, certain personal attributes need to be identified as every patient has different characteristics, health conditions and responses to medicine. Developing new drugs or solutions would require crucial personal details in order to enhance the efficacy and safety. Also, a patient's environmental or regional conditions may also affect their health, which would require information such as their home address and day-to-day itinerary (Chang 2020).

In addition, attempts to nurture data-fueled research and application have failed to create a nationwide data network, as key information is concentrated in a handful of state-designated hospitals. Permitting only a small number of "data-focused" hospitals to leverage patient information has strongly limited the scope of innovation in the country, compared to small bio firms and healthcare start-ups in the U.S. and Israel.

To create a leading bio-health industry, fundamental changes are needed to current regulations to establish an open innovation system. It is absolutely essential to minimize barriers to sharing data for health system management, statistics, research and other health-related purposes that serve the public interest while protecting privacy and data security (OECD 2019). Fast regulatory changes and clarification are needed to provide guidance to the biohealth industry as the concept and scope of industrial and commercial purposes of data usage under PIPA remains ambiguous.

We suggest the following actions:

First, it is imperative to remove excessive restrictions under the Bioethics Act and the oversight of the Bioethics Committee. In particular, a separate set of privacy regulations under a special law should govern biological and medical information to allow flexibility and creativity in data usage for scientific research. If there is a conflict with the Medical Law or Bioethics Law, the Special Law would take precedence.

Second, the processing of sensitive materials and data such as biospecimen and patient information should be permitted in research and secondary usage as a general rule, under a broad consent mechanism and effective safeguards. As in the United States, South Korea needs to adopt a broad consent system that permits researchers to use identifiable biospecimens and data without the requirement to obtain additional consent for future storage, maintenance, or research, as long as the future activities are within the scope of the initial consent (U.S. Department of Health & Human Services 2017). In order to protect individual rights and privacy on personal information, an opt-out mechanism should be put in place, enabling the retraction of information upon request. For instance, the UK's National Health Service (NHS), in 2018, introduced a system that allows patients to "opt out" of their confidential information being used in research.

However, this also means their information can be used in research by default, unless they explicitly decide against it.

| |
|---|
| Personal Information Protection Act (PIPA)<br>PIPA was recently revised to allow pseudonymized information to be used without consent for research purposes. However, while most personal information or financial information such as social security numbers and phone numbers are composed of text and digits, biological and medical information are categorized as “sensitive personal information” derived from a person's unique physical and behavioral characteristics such as a fingerprint, signature, vein pattern, face, voice, iris, and DNA. Thus, the Bioethics Act has been the<br>(Article 2, 17 and 18 of the Bioethics Act) |

Third, new legislation is needed to promote active sharing and exchange of biospecimens and data across medical actors including hospitals, clinics, research centers and private institutions, allowing them to request and receive data upon request. Data sharing has become vital in novel clinical trials to assess the efficacy and safety of emerging therapies and diagnostics.

Currently, the use of health and patient information is limited to state-designated institutions, which are mostly large, university hospitals. Since 2018, South Korea has allowed only 39 hospitals to utilize medical data in research and the development of new treatments, drugs, medical solutions and technologies. The government aims to select five more “data-focused” hospitals in 2020. However, limiting the number of players has led to the monopolization of patient data. Our interviews with regulatory and medical experts have found large hospitals tend to be reluctant to share their data or other such vital information with other institutions. This effectively hinders the growth of an ecosystem of collaboration and open innovation.

At present, there is no law that permits sensitive information from public and private medical institutions to be shared or integrated for the purpose of clinical research (Personal Information Protection Commission 2016), however this mechanism is essential -- from gaining deep insights and new knowledge to developing breakthrough medical treatments and optimizing services to provide personalized, quality health care. Thus we suggest data be combined through a nationally-designated institution equipped with adequate security facilities.

Also, revisions should be made to the Medical Services Act which currently limits the management of patient records, including electronic medical records (EMR), to medical personnel and institutions. We propose that individuals and firms providing health-related services should also be allowed to collect, manage and exchange health and biometric information from electronic devices, and even combine different information from other platforms and devices to gain new, holistic insights on patients’ health. In the U.S., health planning companies are helping digital health start-ups test their products in real-world clinical environments by providing access to de-identified data on 4.5 million of their members across three states. Also, bioinformatics companies can develop software and algorithms that help companies optimize the quality of their data in next generation sequencing (NGS), for instance. These services would not only

benefit developers, but also provide a whole new market for start-ups and SMEs to develop bioinformatics solutions, as software does not require as much heavy research and investment as other areas of biotech.

Furthermore, a clear national mechanism should be established to set a common, compatible standard for medical data use, storage, transfer, and protection, using technologies such as blockchain. Data-focused hospitals in South Korea have developed their own standards, tools and software to collect and make use of biospecimen and patient data, meaning they are not compatible with platforms in other medical institutions. Thus, by setting standards to ensure the optimal quality, accessibility and interoperability of patient and health data across diverse medical organizations, data can be better managed, utilize and protected. Blockchain could facilitate verified access to EHRs, by medical institutions and researchers, securing and tracking each "transaction" transparently, all the while allowing data subjects control over their information and verify how it is shared (Pauwels and Grevatt 2017).

Also, misuse or unauthorized access to data should be clearly defined and also be subject to stronger punishment. This is particularly important in digital health technologies and services, especially telemedicine. Over the last decade, the use of telemedicine has grown significantly throughout the world as an effective, accessible form of healthcare, especially in countries with burgeoning elderly populations and an increasing burden on the public health insurance system. There has also been growing interest in remote consultations and therapy, as most of the world's population are becoming more and more comfortable with using digital solutions than making in-person appointments. While doctor-patient telemedicine is banned in South Korea, under Article 34 of the Medical Act, the need for remote medical services was further highlighted by the coronavirus pandemic, with government authorities temporarily allowing phone consultations between doctors and patients to reduce risk of infection. South Korea's Centers for Disease Control and Prevention said there were 242 cases of phone consultations until March 10th and a survey of 906 remote patients found 87 percent were satisfied with the services. However, attempts to adopt telemedicine by the government has been thwarted by fierce opposition by mostly small clinicians and civic groups. It is essential to address the issue of liability, as well as set standards on clinical protocol, safety measures and patient data management to help mitigate the biggest concerns surrounding telemedicine in the country.

Fifth, various initiatives are needed to strengthen public awareness and determine the level of social consensus on data and privacy. Generally speaking, in the South Korean society, there is distrust towards the adoption and governance of new technologies and the fairness in distributing the benefits of innovation. This low level of social credibility adversely affects social acceptance of the data and AI-based bioeconomy, while creating an environment that hinders the spread of innovation outcomes and benefits across society. Therefore, in order to bolster the data-AI-based bioeconomy, it is very important to actively promote social acceptance by increasing social credibility in the following ways (Choi 2019):

From the perspective of consumers, it is necessary to reinforce awareness of the public interest and social values of biodata and bioeconomy, and to create a legal and institutional environment that emboldens citizens' right to self-determination about health and medical information. The biohealth ecosystem, in which biodata determines competitiveness, has insurmountable potential to advance public interest and social value because it is directly connected to human health and life. In addition, public initiatives should aim to achieve an overall culture change in sharing biomaterial and information, empowering citizens to exert their ownership and control over their data for the advancement of public health and science, benchmarking the UK, US and Canada's 'Personal Genome Project' which encourages individuals to share their genomic data, traits and cells for free to create a global database for research.

In Korea, public institutions such as the National Health Insurance Corporation hold a great volume of patient data, so the possibility of creating public interest and social value through utilization is also very high. Therefore, if people become more aware of the value of their data and the right to control and contribute their health information, the bio ecosystem would be greatly bolstered.

Next, it is necessary to provide policy support to boost the credibility of the data handling system which is critically lacking in public trust. For this, the distribution structure of benefits that arise from using biodata must be established clearly and fairly with the purpose of promoting and advancing public health and well-being. If data suppliers including patients and health service users trust that the distribution of benefits is fair, they would actively contribute and allow the sharing of more data, thereby increasing individual consumer utility as well as advancing public health for society as a whole.

Furthermore, the government should refine and strengthen its mediating role between interested parties such as the medical, industrial, and civil society organizations, and build the credibility of policies and enforcement. Even though nearly eight in ten citizens surveyed were in favor of using personal biodata for public interest, only eight percent trust the 'government's policies and societal system.' Most were hesitant due to concerns about the fairness of penalties and punishment upon misuse or breaches of data and were sceptical about the distribution of benefits. Thus, it is very important to establish a balanced protection policy system that supports fair and safe sharing and use of biodata, all the while promoting effective utilization.

South Korea's bio-health sector stands at a critical inflection point. Through reflexive regulatory reform, the country must act quickly to harness its strengths in digital infrastructure, hospital networks, data and skilled medical personnel while overcoming barriers to R&D and innovation. The prospects are bright but fundamental changes are crucially needed.

## CHAPTER 4: CONCLUSION & DISCUSSION

South Korea is endowed with a state-of-the-art industrial landscape, boasting of the latest infrastructure and world-class research facilities. The top-level hardware, however, continues to operate on a software designed for industries of the past, retaining the fundamental spirit of regulatory restrictions, risk averse culture, and a lack of social dialogue and democracy on adopting new technologies. An innovation ecosystem is long overdue, yet the government's key economic strategy maintains the top-down model of growth that is well past its sell-date. The Korean New Deal Strategy is largely focused on state-led job creation and expansion of public services, investing which will create 1.9 million jobs by investing a total of KRW 160 trillion ($133.1 billion) by 2025. The proposed budget for 2021 injects KRW 30.6 trillion in job creation, an annual increase of 20 percent, while spending only KRW 27 trillion in R&D and cutting expenditure in Education by 2 percent. Meanwhile, genuine social needs for innovation in areas like telemedicine and data-based technologies continue to be unmet. For South Korea to make meaningful progress toward sustainable growth as an advanced economy and society, it must take the leap to become an entrepreneurial state through greater support and incentives for research and education, and a society-wide innovation ecosystem, rather than rely on shot-in-the-arm solutions.

Thus, the measures we proposed for South Korea in 2018 remain consistent today (Lee J. and Choi C. 2018), but the need to adopt a bottom-up ecosystem is now more pressing than ever. In fact, as a growing number of countries actively adopt and overtake South Korea in designing new regulatory frameworks to accommodate Industry 4.0, our suggested measures stated below can be followed as a guideline in other jurisdictions.

First, the government must quickly identify and remove red tape by streamlining existing regulations and regulatory authorities. Regulatory overlaps, overcomplicated procedures, and the common top-down mode of governance commonly found in bureaucracy often slows or even stifles innovative activities, especially the development of new products and services. This dampens sustainability and growth for research and business alike, especially for those operating on a smaller capacity as they do not have the resources to work through time-consuming and financially exhausting approval procedures, or other such regulatory barriers. Thus, an integrated regulatory system should provide clear and common guidelines, grounds, provisions, and mechanisms to minimize confusion and hindrances for key developers of emerging technologies. Furthermore, it is worth considering additional measures to remove jurisdictional conflicts as well as micromanagement on R&D activities.

Second, scientists and researchers should have a greater voice in each stage of regulatory design, participating in key bodies and platforms for regulatory reform on R&D. We proposed the establishment

of a separate council dedicated to the task, where field researchers actively participate and contribute their expertise. The body should evaluate regulatory impact, deliberate new regulations, and amend or scrap existing regulations. In order to create the optimal environment for innovative R&D, the input of field experts with first-hand knowledge and experience is vital as they can offer deep insights and practical solutions. Also, as they are likely to promote and adopt industry standards, such regulations would be better received and followed by the scientific community, increasing positive outcomes and reducing compliance costs.

Third, regulatory power should be expanded and delegated to standard-setting organisations and research institutes in science and technology. Industry-defined standards can allow for self-regulation, aiding better compliance and performance among the players. Self-regulation and oversight can typically be conducted in research ethics (such as standards on academic integrity, plagiarism, records of data and cited information, and etc.) as well as research expenses and management. These regulations tend to be based on sub-administration rules or regulations, rather than statutes, so few legal issues would arise from the delegation of regulatory authority. Science and technology is, in fact, a field in which industry standards are commonly used, and it is comparatively easier for the members to establish a consensus among the members. This could enable the science and tech industry to, further, develop and abide by its own guidelines on social and ethical issues, in a form of self-regulation. For instance, the UK's General Medical Council (GMC), a regulatory body for medical practitioners, is responsible for developing standards in education and training, as well as codes of conduct and investigating patient concerns. The council was delegated the responsibility of standard-setting, as the highly-specialized, technical nature of the profession requires significant area-specific expertise (UK Dept for Industry Strategy 2019).

Fourth, ethical standards must be developed and rationalized by social consensus. As ethics is a social construct, it is crucial to include and heed public opinion as the Fourth Industrial Wave not only causes technological changes but also disrupts societal order and gives rise to unprecedented ethical challenges. This is in line with the principle of deliberative democracy that encourages the collective intelligence of ordinary citizens and facilitates public awareness, allowing for social problem-solving. In doing so, it is essential to overcome the information asymmetry that exists between experts, governments, and citizens and promote well-informed opinions. In this regard, citizens must have access to sufficient and accurate information on the issue at hand which should be presented transparently as informational content and audio-visual materials through various formats, such as storytelling, narratives, and entertainment content. Furthermore, to reflect public opinion in regulatory discourse, opinion surveys and social media platforms for dialogue are possible tools that could be utilized.

Going forward, open innovation cannot occur without a system-wide change that involves all actors of society. Governments must reform themselves from being rigid, formalistic, authoritative, and excessively controlling bureaucracies, to flexible and adaptive enablers of innovation. Authorities should commit to the spirit of civil servanthood and mediating the innovation process, both accommodating and keeping in check researchers and corporations, as well as encouraging citizen participation in deliberating regulations (Lee J. and Choi C., 2018). Meanwhile, for industry and academia, their propensity to avoid or minimize risk and responsibility should be replaced with risk-taking, forward-thinking mindsets that are strongly geared towards social objectives. Lastly, and most crucially, citizens must make the shift from being mere consumers to becoming active contributors that shape and regulate disruptive technologies.

It is clear that the top-down system of regulation that governed the previous industrial era is no longer relevant today nor can it support sustainable growth in the modern world economy. The first step in the path of innovation must be taken together by all stakeholders to harness the waves of changes of the Fourth Industrial Revolution, and make the leap from fast-follower to first mover amid the rapidly changing dynamics of the global economy.

**References**


Bew, Paul. 2020. "Sixteenth Report Of The Committee On Standards In Public Life". London: Controller of Her Majesty's Stationery Office. http://Sixteenth Report of the Committee on Standards in Public Life.

Bonvillian, William, Richard Van Atta, and Patrick Windham. 2019. The DARPA Model For Transformative Technologies: Perspectives On The U.S. Defense Advanced Research Projects Agency. Open Book Publishers.

Blind, Knut & Petersen, Sören S. & Riillo, Cesare A.F., 2017. "The impact of standards and regulation on innovation in uncertain markets," Research Policy, Elsevier, vol. 46(1), pages 249-264.

Bryant, John. 2006. "Bioethics Briefing: Stem Cells." Edited by Chris Willmott. University of Leicester. Higher Education Academy, Centre for Bioscience. https://www2.le.ac.uk/projects/genie/downloads/ethicsbrief5.pdf.

Chang, JH, H Moon, J Oh, JH Kim, CI Kim, and J Yang. 2020. Regulatory Reform in Korea Interview by Sooyoung Oh.

Choi, Injun. 2020. "Presidential 4Th Industrial Revolution Committee Held One AI Meeting In A Year And 8 Months.(文대통령 직속 '4 차산업혁명위원회' AI 회의는 1 년 8 개월간 딱 한번 열었다)". Chosun Ilbo. https://biz.chosun.com/site/data/html_dir/2019/05/03/2019050300242.html.

Choi, Kyoungsuk. 2019. "Regulation on Cell and Gene Therapy in Korea." Presentation.

Choi, Yoon-hee. 2019. "Status and Challenges Regarding Social Acceptance of Biodata Sharing in South Korea." KIET Issue Paper.

Cohen, Boyd. 2016. The Emergence of the Urban Entrepreneur : How the Growth of Cities and the Sharing Economy Are Driving a New Breed of Innovators. Santa Barbara, California: Praeger, An Imprint Of Abc-Clio, Llc.

Department for Digital, Culture, Media & Sport. n.d. "Digital Charter." GOV.UK. Department for Digital, Culture, Media & Sport. Accessed July 20, 2020a. https://www.gov.uk/government/publications/digital-charter/digital-charter.

Human Tissue Authority. 2008. "STEM CELL SCIENCE IN THE UK." London: Human Tissue Authority.

IbisWorld. n.d. "Telehealth Services in the US Market Size 2005–2025." Ibisworld. Ibisworld. Accessed May 24, 2020b. https://www.ibisworld.com/industry-statistics/market-size/telehealth-services-united-states/.

Israel Innovation Authority. n.d. "Early Stage Companies Incentive Program." Israel Innovation Authority. Israel Innovation Authority. Accessed July 20, 2020c. https://innovationisrael.org.il/en/program/early-stage-companies-incentive-program#:~:text=The%20Early%20Stage%20Incentive%20Program.

Jeong, Sae-im. 2019. "4 Firms to Offer up to 56 Direct-to-Consumer Genetic Testing Services - Korea Biomedical Review." Www.Koreabiomed.Com. December 19, 2019. http://www.koreabiomed.com/news/articleView.html?idxno=7035.

Jung, Wonhyup. 2020. ""It's Not As Simple As Requesting Regulatory Waivers" ("규제 풀어달라 주장만으론 안 돼" 규제샌드박스 전문변호사가 말하는 A To Z)". Joongang Ilbo. https://news.joins.com/article/23777478.

Kim, Jihyun. 2019. "South Korea to Fast Track New Drug Approval, Clinical Stem Cell Therapy Research." BioWorld. BioWorld. August 14, 2019. https://www.bioworld.com/articles/429487-south-korea-to-fast-track-new-drug-approval-clinical-stem-cell-therapy-research?v=preview.

Korea Economic Research Institute. 2019. "'2019 Survey On Impact Of Regulatory Reform (2019 년 규제개혁체감도 조사 결과표)'". Seoul: Korea Economic Research Institute.

Korea Health Industry Development Institute. 2019a. "2018 Korea Health Industry Facts&Figures." Korea Health Industry Development Institute. Osong: Korea Health Industry Development Institute. https://www.khidi.or.kr/board/view?pageNum=3&rowCnt=10&no1=325&linkId=48792558&titleId=391851&menuId=MENU02183&maxIndex=00488283819998&minIndex=00487228189998

&schType=0&schText=&schStartDate=&schEndDate=&boardStyle=&categoryId=&continent=&country=.
Lee, Ju-Ho, and Changyong Choi. 2018. “혁신생태계 조성을 위한 규제개혁 (Regulatory Reform to Foster Innovation Ecosystem).” KDI Working Paper 2018-02. June, 2018. https://ssrn.com/abstract=3439950.
Lee, J. 2020. "Genetic Testing Service Has Not Been Able To Start For Over A Year (유전자검사 서비스 1 년 넘게 출발도 못해…의약품 원격판매 '화상투약기' 7 년째 표류)". Korea Economic Daily. https://www.hankyung.com/it/article/2020042341791.
Lee, Munjae. 2018. “Strategies for Promoting the Medical Device Industry in Korea: An Analytical Hierarchy Process Analysis.” International Journal of Environmental Research and Public Health 15 (12): 2659. https://doi.org/10.3390/ijerph15122659.
Malyshev, Nick. 2019. “Regulatory Effectiveness in the Era of Digitalisation.” OECD.
McEntaggart, Kate, Julien Etienne, and Jennifer Uddin. 2019. “Designing Self-and-Co-Regulation Initiatives: Evidence on Best Practices.” London: UK Government.
Milburn, Alan. “Technology and Innovation Are Key to Saving the NHS.” The Guardian. Guardian News and Media, October 21, 2017. https://www.theguardian.com/commentisfree/2017/oct/22/technology-and-innovation-key-to-saving-the-nhs.
Millard, Nathan. 2019. "Investment In Korea’S Venture Ecosystem Is Booming". Techinasia.Com. https://www.techinasia.com/investment-korea-venture-ecosystem-booming.
Ministry of Land, Infrastructure and Transport. 2020a. Act On Parks, Green Areas And Etc. Vol. 50.
Ministry of Science and Technology, Institute for Information & Communications Technology Promotion. 2019. "'Study on Status of Companies Participating In Start-Up & Venture Support Projects'". Policy Study on Broadcast & Communication. http://Institute for Information & Communications Technology Promotion.
Ministry of SMEs and Startups. 2017. “2017 Start-Up Support Projects (2017 창업지원사업).” Daejeon: Ministry of SMEs and Startups.
Ministry of SMEs and Startups. 2020. "2019 Survey Of Korea Venture Firms". Daejeon: Ministry of SMEs and Startups.
National Health Service. 2019. “Sharing Your Health Records.” NHS. 2019. https://www.nhs.uk/using-the-nhs/about-the-nhs/sharing-your-health-records/.
Personal Information Protection Committee. 2016. “Research on the Improvement of Laws and Systems for Processing the Purpose of Research of Personal Information.” Seoul: Personal Information Protection Committee.
Richter, Gesine, Michael Krawczak, Wolfgang Lieb, Lena Wolff, Stefan Schreiber, and Alena Buyx. 2017. “Broad Consent for Health Care–Embedded Biobanking: Understanding and Reasons to Donate in a Large Patient Sample.” Genetics in Medicine 20 (1): 76–82. https://doi.org/10.1038/gim.2017.82.
Roberts, Sam. 2019. "How Roundtables Are Helping Inform The National Data Strategy". Department For Digital, Culture, Media And Sport Blog. https://dcmsblog.uk/2019/07/how-roundtables-are-helping-inform-the-national-data-strategy/.
Song, K. 2020. "젊은 과학자 56% "정부 R&D 선정 평가위원 전문성 떨어져" 지적". Maeil Business Newspaper. http://vip.mk.co.kr/news/view/21/20/1796993.html.
South Korean government. 2019b. “Innovative Strategy on the Bio-Health Industry.” Sejong: South Korean government.
Stanford Center for Digital Health, and Rock Health. 2019. “Digital Health Consumer Adoption Report 2019.” Rock Health. https://rockhealth.com/reports/digital-health-consumer-adoption-report-2019/.
"The Public Bodies (Abolition Of The National Endowment For Science, Technology And The Arts) Order 2012". 2020. UK Legislation. Accessed August 1. https://www.legislation.gov.uk/uksi/2012/964/made.

Understanding Patient Data. 2020. “How Do People Feel about the Use of Data?” Understanding Patient Data. Wellcome Trust. 2020. https://understandingpatientdata.org.uk/how-do-people-feel-about-use-data.

Park, Young-Taek, and Dongwoon Han. 2017. “Current Status of Electronic Medical Record Systems in Hospitals and Clinics in Korea.” https://doi.org/10.4258/hir.2017.23.3.189.

Pauwels, Eleanore, and Nathaniel Grevatt. “The Social Benefits of Blockchain for Health Data: Securing Patient Privacy and Control,” November 2017. https://www.wilsoncenter.org/publication/the-social-benefits-blockchain-for-health-data-securing-patient-privacy-and-control.

Yu Myeong-Hee. 2018. “혁신생태계 조성을 위한 규제개혁 (Regulatory Reform to Foster Innovation Ecosystem).” KDI Working Paper 2018-02. June, 2018. https://ssrn.com/abstract=3439950.